

REMARKS

Claims 1-20, 22-31 and 38-95 are currently pending. Claims 1, 20, 22, 53 and 71-72 have been amended to an upper limit pH of 3.0. Support for the amendments to the claims is seen on page 16, Table 1. Claim 21 has been cancelled. Applicants maintain that no new matter has been added thereby and therefore request that these amendments be entered.

Rejection under 35 USC 102(b):

Claims 1-31, 50, 53-80 and 93 are rejected under 35 USC 102(b) as being anticipated by Freund *et al* (DE 19653969) (US 2001/0008632 is being used as the translation for the German document).

Freund claims an aqueous pharmaceutical preparation in the form of a solution. Paragraph [0055] of Freund specifies, “[t]he solutions are set to a pH of 3.2 to 3.4 with 0.1 or 1N HCl.”

The subject specification exemplifies formulations in Table 1 all having a pH of 3.0. The claims in the subject application specify a pH between 2.0 and 3.0.

To anticipate a claim, a single source must contain all of the elements of the claim. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984); *In re Marshall*, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (C.C.P.A. 1978). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. See *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984).

In the Response to Arguments the Examiner states, “[t]he two pH values are close enough...”. A pH of 3.2 is not equal to a pH of 3.0 and “close enough” is not the rule to anticipate a claim.

Accordingly, there is no anticipation of the claimed invention by Freund *et al.* and applicants respectfully request that the Examiner reconsider and withdraw this rejection.

(b) The Examiner also rejected claims 1-19, 23-30, 50, 53-70 and 93 under 35 U.S.C. § 102(b), as allegedly anticipated by Bozung *et al.* (DE 19921693; U.S. Patent No. 6,433,027 being used as a translation thereof).

Bozung *et al.* is directed at pharmaceutical compositions comprising combinations of Beta sympathomimetics and anticholinergics. The formulations listed in column 7 in Bozung *et al.* specify a pH of 3.4, no other pH is claimed or disclosed in Bozung.

The subject specification exemplifies formulations in Table 1 all having a pH of 3.0. The claims in the subject application specify a pH between 2.0 and 3.0.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co.*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); *see also* M.P.E.P. § 2131. Accordingly, the rejection under Section 102(b) should be reconsidered and withdrawn.

Rejections under 35 USC 103(a):

The Examiner rejected claims 38-49, 51, 52, 81 to 92, 94, and 95 under 35 U.S.C. § 103(a), as allegedly unpatentable over Freund *et al.* as applied to claims 1-31, 50, 53-80 and 93 above, and further in view of Weston *et al.* (WO 91/14468).

In response, applicants have amended the claims so that neither Freund *et al.* nor Weston *et al.*, alone or in combination, renders the pH of applicants claimed invention and therefore does not provide any disclosure or embodiment of the claimed invention.

Since the Examiner is relying solely on Freund *et al.* to teach the formulation to be used in the nebulizer of Weston *et al.*, applicant maintains that neither Weston nor Freund alone or in combination teaches the formulation used in applicants' claimed invention.

The Examiner has failed to establish a *prima facie* case of obviousness against the instant invention, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Obviousness-type Double Patenting:

Claims 1-31, 50, 53-80 and 93 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of US 6,908,928 in view of Freund et al (US 2001/0008632).

In view of the arguments outlined in the paragraphs above with reference to the pH levels claimed, Applicants believe that the rejection is rendered moot and withdrawal of the same is respectfully requested.

In view of the above amendments and remarks, Applicants respectfully submit that this application is now in condition for allowance and earnestly request such action.

If any points remain at issue which can best be resolved by way of a telephonic or personal interview, the Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

/wendy petka/
Wendy Petka
Attorney for Applicants
Reg. No. 53,459

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877
Tel.: (203) 798-6614
Fax: (203) 798-4408